



19-FEB-1998-0708

McN

McNEIL CONSUMER
FORT WASHINGTON

Page

Individual Safety Report



3031799-7-00

A. Patient information				C. Suspect medication(s)			
1. Patient identifier Case 284 in confidence	2. Age at time of event: 61 yrs or Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown acetaminophen product #2 aspirin			
B. Adverse event or product problem 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) 2. Outcomes attributed to adverse event (check all that apply) (X) death (mc/day/yr) unknown () disability () life-threatening () congenital anomaly (X) hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage () other: 3. Date of event unknown (mc/day/yr) 4. Date of this report 02/06/98 5. Describe event or problem Case # 284 received from the [redacted] 1996 case fatality data. See attached case report form provided by [redacted] 6. Relevant tests/laboratory data, including dates See attached case report form provided by [redacted] 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) See attached case report form provided by [redacted]				2. Dose, frequency & route used #1 unknown dose, po #2 unknown dose, po		3. Therapy dates (if unknown, give duration; from/to, or best estimate) #1 unknown date; 1 day #2 unknown date; 1 day	
				4. Diagnosis for use (indication) #1 unknown #2 unknown		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
				6. Lot # (if known) #1 Unknown #2 unknown	7. Exp. date (if known) #1 Unknown #2 unknown	8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
				9. NDC # - for product problems only (if known)			
				10. Concomitant medical products and therapy dates (exclude treatment of event): See attached case report form provided by [redacted]			
G. All manufacturers							
1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-233-7820			
4. Date received by manufacturer (mc/day/yr) 01/30/98				5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes			
6. If IND, protocol #				3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:			
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #				8. Adverse event term(s) OVERDOSE COMA HYPERGLYCEMIA HYPOTENSION SHOCK LIVER FUNC ABNO HEART ARREST DEATH			
9. Mfr. report number 0929297A							
E. Initial reporter							
1. Name, address & phone # [redacted] MD [redacted] Centers Suite [redacted] Avenue [redacted]							
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			

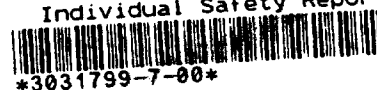


Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



19-FEB-1998-0709



3031799-7-00

[REDACTED] FATALITY: 1996 [REDACTED]

Case Number: 284
Age: 61 yrs
Substances: Aspirin
acetaminophen
Chronicity: Acute
Route: Ingestion
Reason: Int Unknown
Pre-Hospital Arrest? No

This 61 yo female ingested an unknown amount of an unknown substance one to five hours before being found unresponsive. She was taken to a local ED where she arrived comatose. Her initial temperature, vital signs, oxygen saturation and blood pH were all normal. She was given naloxone and flumazenil without response. An NG tube was placed and lavage done without pill return. The poison center was contacted at this time. The patient was noted to have pinpoint pupils and an elevated blood sugar of 246mg/dl. A CT scan of the head was negative. A salicylate level drawn in the ED was 87 mg/dl (2-7 hours post ingestion). The patient was transferred to a tertiary care facility for dialysis.

The patient arrived at the tertiary care facility 4 hours post presentation. Acetaminophen level here was 531 mcg/ml (5.5-11 hours post ingestion). She was started on Mucomyst and underwent dialysis. Salicylate levels dropped to 33 mg/dl after four hours of dialysis. Oral Mucomyst was continued. Shortly after dialysis the patient developed hypotension and cardiogenic shock. This was believed to be due in part to some preexisting cardiac compromise. Liver enzymes became elevated but this was felt to be due more to poor perfusion than acetaminophen toxicity. Despite maximum pharmacologic support, the patient suffered cardiopulmonary arrest unresponsive to code medications and expired 18 hours post presentation (19 to 24 hours post ingestion). The patient's spouse refused the request for an autopsy.